UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RACHAEL MAHER, JASMIN AMARO, MARINA GOMEZ, REBECCA TORRES, GLORIA URIBE, CAROLYN GILL, MARY JO BARNES, BRITTANY BONDS, TERESA FAUGHNAN, LUZ VARGAS, EBONY ODOMMORRIS, JENNIFER MALTESE, and LISA BRADY, individually and on behalf of others similarly situated, Plaintiffs, v. AMAG PHARMACEUTICALS, INC., Defendants.	**Civil Action No. 20-152 (JXN) (JBC)** **OPINION**

NEALS, District Judge:

This matter comes before the Court on Defendant AMAG Pharmaceuticals, Inc.'s ("AMAG") motion to dismiss Plaintiffs' second amended complaint (ECF No. 66) (the "Second Amended Complaint") pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 79). Plaintiffs opposed (ECF No. 87), and AMAG replied. (ECF No. 88). Jurisdiction and venue are proper pursuant to 28 U.S.C. §§ 1332 and 1391(b), respectively. The Court has carefully considered the parties' submissions and decides this matter without oral argument under Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1(b).

For the reasons stated below, AMAG's motion to dismiss (ECF No. 79) is **GRANTED in part** and **DENIED in part**. AMAG's motion to consolidate and to stay pre-trial deadlines (ECF No. 107) is also **GRANTED**.

I. BACKGROUND[1]

This putative class action "arises from [AMAG's] marketing and sale of the prescription drug Makena, a hydroxyprogesterone caproate." (SAC ¶ 1). Plaintiffs reside in California, Kansas, New Jersey, New York, Missouri, and Wisconsin and were "prescribed, injected with, and purchased Makena." (*Id.* ¶¶ 2, 5, 9, 11, 14, 18, 21, 24).

Hydroxyprogesterone caproates, like Makena, have "been in the U.S. marketplace since 1956." Following a "clinical trial published in 2003 by the National Institute of Child Health and Human Development (the 'Meis study')[,]" which "appeared to find that it might reduce the risk of preterm births in at-risk mothers[,]" the public's "[i]nterest in hydroxyprogesterone caproate[s]" increased. (*Id.* ¶ 51). Ultimately, the drug was "rebrand[ed] as Makena . . . ." (*Id.* ¶ 55).

Following the United States Food and Drug Administration's ("FDA") approval, Makena "hit the U.S. market in early 2011." (*Id.* ¶ 63). However, remaining on the market "was conditioned on" a "long-term clinical trial to confirm the efficacy of hydroxyprogesterone caproate in preventing preterm births" known as the Progestin's Role in Optimizing Neonatal Gestation (the "PROLONG study"). (*Id.* ¶¶ 111-12). According to Plaintiffs, AMAG was aware before the PROLONG study was released that "Makena was ineffective." (*Id.* ¶ 112).

As a "Collaborator" and "Sponsor" of the PROLONG study, AMAG "was legally obligated to monitor the progress of the PROLONG study[,]" analyze data, and had "access to all study records" in "the event of an audit . . . ." (*Id.* ¶¶ 113, 119-21, 124, 126) (emphasis removed). Were an audit to occur, AMAG would be provided "written documentation of continued review of the clinical research" concerning the PROLONG study. (*Id.* ¶ 125) (emphasis removed).

[1] The following factual allegations are taken from the Amended Complaint, which for purposes of a motion to dismiss are accepted as true. *Sheridan v. NGK Metals Corp.,* 609 F.3d 239, 262 n.27 (3d Cir. 2010).

AMAG was also required to "review and evaluate the evidence relating to the safety and effectiveness of the drug" to the FDA. (*Id.* ¶ 127) (emphasis removed).

On March 8, 2019, AMAG released the PROLONG study, which concluded that "[t]here were [] no statistically significant differences concerning miscarriages and stillbirths between Makena and the placebo treatment." (*Id.* ¶ 143, 145). This "confirmed what the Meis study suggested[;]" that Makena "failed to reduce the risk of preterm birth." (*Ibid.*). In other words, the PROLONG study proved that "Makena does not work." (*Id.* ¶ 146).

On October 29, 2019, Dr. Julie Krop, AMAG's former "Chief Medical Officer," informed the FDA's "Bone, Reproductive, and Urologic Drugs Advisory Committee" that the "Data and Safety Monitoring Board []" already "knew the overall event rate." (*Id.* ¶¶ 129, 134) (internal quotations and brackets omitted). This confirms that AMAG knew Makena was ineffective. (*Id.* ¶ 135). Patients also informed AMAG that Makena was ineffective. (*Id.* ¶¶ 136, 140). Thus, AMAG knew Makena did not work "before the results of" the PROLONG study. (*Id.* ¶¶ 147-48).

AMAG "markets directly to pregnant women" like Plaintiffs. (*Id.* ¶ 173). Their "false and deceptive" statements include, "Makena helps you get closer to term . . . ." (*Id.* ¶¶ 173, 192) (internal quotations and ellipses omitted). AMAG's "direct to patient marketing utilizes testimonials" of previous patients and "education[al] brochure[s] that highlight Makena's "effectiveness[.]" (*Id.* ¶¶ 174-75). During treatment, Plaintiffs "received marketing materials" in "shipment[s] of Makena" and "pamphlets about Makena in [their] doctor's offices[;]" "reviewed the Makena website[;]" and had telephone conversations with AMAG's and "Makena Care Connection['s]" representatives regarding the "instructions and benefits of Makena . . . ." (*Id.* ¶¶ 15-16, 22, 25-27, 34, 41).

"But for" AMAG's "misleading[,] [] deceptive statements[,]" and "material omissions[,]" Plaintiffs "would not have purchased and been injected with Makena." (*Id.* ¶ 177). Plaintiffs allege that "AMAG's misrepresentations and material omissions" misled Plaintiffs; and were a "substantial factor in influencing" their "decision[] to purchase and be injected with Makena." (*Id.* ¶ 181). Plaintiffs paid "hundreds of dollars for each shot of Makena." (*Id.* ¶ 78).

Plaintiffs allege violations of the following state statutes: (i) the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.* (the "CFA") (Count One); (ii) the Cal. Bus. & Prof. Code § 17200, *et seq.* (the "UCL") (Count Two); (iii) the California Consumer's Legal Remedies Act, Cal Civ. Code § 1770, *et seq.* (the "CLRA") (Count Three); (iv) the Kansas Consumer Protection Act, Kan. Stat. Ann § 50-623, *et seq.* (Count Four); (v) the Missouri Merchandising Practices Act, RSMo § 407.010, *et seq.* (the "Missouri Act") (Count Five); (vi) the New York General Business Law § 349(a) (the "New York Business Law") (Count Six); (vii) the Wisconsin Deceptive Trade Practices Act, Wis. Stat. §§ 100.18(a), 11(b)(2) (Count Seven); and violation of the (viii) Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO") (Count Eight).

II. PROCEDURAL HISTORY

On January 3, 2020, Plaintiffs filed the initial complaint. (ECF No. 1). After four related lawsuits were consolidated into this matter (ECF Nos. 9, 11), Plaintiffs filed an amended complaint (ECF No. 15) (the "Amended Complaint"). Apart from the RICO claim, the Amended Complaint alleged the same causes of action discussed here.

On June 8, 2020, Defendant moved to dismiss the Amended Complaint, which Plaintiffs opposed. (ECF Nos. 25, 32, 35). In that motion, AMAG contended that Plaintiffs' consumer fraud claims were preempted by federal law. (ECF No. 25-1 at 24-29[2]). In support, AMAG argued that:

[2] The Court refers to the ECF page numbers.

(1) AMAG would have to stop selling Makena to comply with state regulations; and (2) AMAG could not unilaterally amend its label to state Makena was ineffective without prior FDA approval. (ECF No. 35 at 9-18). United States District Judge John Vazquez (ret.) agreed with AMAG and dismissed the Amended Complaint without prejudice (Vazquez's May 25, 2021 Op. (ECF No. 62) (the "Vazquez Opinion")), with leave to amend (Vazquez's May 25, 2021 Ord. (ECF No. 63)).

On June 24, 2021, Plaintiffs filed the Second Amended Complaint. On June 30, 2021, this matter was reassigned to this Court. (ECF No. 70). AMAG moved to dismiss the Second Amended Complaint, Plaintiffs opposed (ECF No. 87), and AMAG replied (ECF No. 88) (the "Reply"). AMAG's motion to dismiss is now ripe for consideration.

On March 2, 2023, AMAG removed Plaintiffs Molly O'Hara and Brandy Silas' (together, "O'Hara/Silas") pending matter in 23-cv-21743 from Massachusetts state court to the United States District Court for the District of Massachusetts. (ECF No. 1 in 23-cv-21743 at 1). On March 3, 2023, AMAG filed a motion to transfer venue to this District. (ECF No. 8 in 23-cv-21743). On March 17, 2023, O'Hara/Silas moved to remand and opposed AMAG's motion to transfer venue (respectively, ECF Nos. 13, 16 in 23-cv-21743). AMAG opposed the motion to remand. (ECF No. 17 in 23-cv-21743).

On October 27, 2023, United States District Judge Allison Burroughs denied O'Hara/Silas' motion to remand and granted AMAG's motion to transfer venue. (ECF No. 18 in 23-cv-21743). On October 31, 2023, 23-cv-21743 was transferred to this District. (ECF No. 19 in 23-cv-21743). On December 8, 2023, AMAG moved to consolidate 23-cv-21743 into 20-cv-152 (ECF No. 107), which is also ripe for consideration.[3]

[3] AMAG has not moved to dismiss in 23-cv-21743.

III. LEGAL STANDARD

Rule 8 requires that a pleading include "a short and plain statement of the claim showing that the pleader is entitled to relief" and provide the defendant with "fair notice of what the claim is and the grounds upon which it rests[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation and internal quotations and ellipses omitted). However, when pleading fraud claims, greater specificity is required. *See* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). *Ibid.* To meet the heighted pleading requirements, plaintiffs must "state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged and plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Alpizar-Fallas v. Favero*, 908 F.3d 910, 919 (3d Cir. 2018) (citation and internal quotations and brackets omitted).

On a Rule 12(b)(6) motion, the "facts alleged must be taken as true" and a complaint may not be dismissed merely because "it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (citation omitted). A complaint will survive a motion to dismiss if it provides a sufficient factual basis to state a facially plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To determine a complaint's sufficiency, the Third Circuit requires a three-part inquiry: (1) the court must first recite the elements that must be pled in order to state a claim; (2) the court must then determine which allegations in the complaint are merely conclusory and therefore need not be given an assumption of truth; and (3) the court must "assume the[] veracity" of well-pleaded factual allegations and ascertain whether they plausibly "give rise to an entitlement for relief." *Santiago v. Warminster Twp.,* 629 F.3d 121, 130 (3d Cir. 2010) (citations omitted).

As to motions to consolidate, courts may consolidate actions "involv[ing] common question[s] of law or fact . . . ." Fed. R. Civ. P. 45(a)(2); *see also A.S. ex rel. Miller v. SmithKline Beecham Corp.*, 769 F.3d 204, 212 (3d Cir. 2014) ("[D]istrict courts have broad power to consolidate cases that share common questions of law or fact.") (citations and internal quotations and brackets omitted).

IV. DISCUSSION

A. AMAG's Motion to Consolidate[4]

Preliminarily, O'Hara/Silas consent to consolidation as do counsel in 20-cv-152. (ECF No. 107-1 at 7). Further, while 23-cv-21743 and 20-cv-152 involve similar allegations but different causes of action (*Id.* at 11-12), they "stem from the same" allegations and "discovery obtained in one lawsuit will undoubtedly be relevant to the other and common questions of law and fact will predominate . . . ." *City of Southfield Fire and Police Retirement System v. Hayward Holdings, Inc.*, No. 23-4146, 2023 WL 8752436 at *2 (D.N.J. Dec. 19, 2023). Thus, consolidation is appropriate. In consolidating the matters, it serves "the interests of justice and judicial economy" (*Gilliam v. Cavallaro*, No. 21-16844, 2023 WL 6049676, at *1 (D.N.J. Sept. 15, 2023)), because discovery will likely be duplicated. (*See* ECF No. 107-1 at 6-7). Accordingly, AMAG's motion to consolidate and to stay pre-trial deadlines (ECF No. 107) is granted.

B. AMAG's Motion to Dismiss[5]

1. AMAG's Preemption Arguments

AMAG argues that federal law preempts Counts One to Seven (AMAG's Br. in Supp. (ECF No. 79-1) ("AMAG's Br.") at 19).[6] In support, AMAG asserts that: (i) this is a "stop-selling"

[4] This Opinion refers to the docket citations in Civil Action No. 2:20-cv-152, unless otherwise stated.
[5] Because AMAG withdrew its primary jurisdiction argument (ECF Nos. 100-01), the Court does not analyze that issue. However, it likely would not have met the test in *Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711 (D.N.J. 2008).
[6] Judge Vazquez's preemption analysis is incorporated here because the parties do not dispute it.

case like *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472 (2013); and (ii) new allegations do not cure deficiencies raised in the Vazquez Opinion, i.e., what AMAG knew before the PROLONG study's release; and when Plaintiffs took Makena. (*Id.* at 38-39). The Court agrees in part.

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citations omitted). "[P]re-emption follows automatically by the operation of the Supremacy Clause" (*Wyeth v. Levine*, 555 U.S. 555, 624 (2009) (Alito, J. & Scalia, J., dissenting)), which "invalidates state laws that interfere with, or are contrary to, federal law." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (internal quotations and citation omitted). "Federal law can preempt state law in three ways: (1) express preemption, (2) field preemption, and (3) conflict preemption." *Farina v. Nokia Inc.*, 625 F.3d 97, 115 (3d Cir. 2010) (citing *Hillsborough Cnty.*, 471 U.S. at 713).

The parties agree that the issue here is conflict preemption, which "nullifies state law inasmuch as it conflicts with federal law, either where compliance with both laws is impossible or where state law erects an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 115 (citation and internal quotations omitted); *compare PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) ("The question for impossibility is whether the private party could independently do under federal law what state law requires of it.") (citation and internal quotations omitted). Conflict or impossibility preemption "is a demanding defense" in the drug labeling context. *Wyeth*, 555 U.S. at 573. A defendant must show that it could not have unilaterally changed its label in any way to add the warning required by state law. *Id.* at 569-71.

There is a "presumption against pre-emption" (*Wyeth*, 555 U.S. at 565 n.3) that applies with special force in fields involving traditional state police powers. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470, 485 (1996) ("In all pre-emption cases, and particularly in those in which Congress

has legislated in a field which the States have traditionally occupied, ... [courts] start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (citations and internal quotations and ellipses omitted). Further, the "mere possibility of impossibility is not enough" to demonstrate impossibility. *PLIVA*, 564 U.S. at 635 (Sotomayor, J., Ginsburg, J., Breyer, J. & Kagan, J., dissenting); *see also Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) (rejecting "hypothetical or potential conflict conflict[.]").

Under *Wyeth*, if there is "clear evidence that the FDA would not have approved" a label change, then it is impossible to comply with both federal and state law; and a plaintiff's failure-to-warn claims are preempted. 555 U.S. at 571. To establish clear evidence, a drug manufacturer must "show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.,* 593 F. Supp. 3d 96, 116 (D.N.J. 2022) (citing *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019)). Here, certain claims are preempted.[7]

a) <u>This is Not a "Stop-Selling" Case</u>

The Code of Federal Regulations ("CFR") permits Changes Being Effected Applications, i.e., "[c]hanges in the labeling to reflect newly acquired information . . . ." 21 C.F.R. § 314.70(c)(6)(iii) (the "CBE exception"). The CBE exception is used to: (1) "[t]o add or strengthen a contraindication, warning, [or] precaution" or (2) "[t]o delete false, misleading, or unsupported indications for use of claims for effectiveness . . . ." § 314.70(c)(6)(iii)(A), (D). "Newly acquired information" is defined as:

[7] The Court does not treat what appear to be "background allegations" concerning safety and compounded drugs (AMAG's Br. at 22-23, 36-37; Reply at 22, 36-37), as formal claims.

> [D]ata, analyses, or other information not previously submitted to the Agency, which may include . . . data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data . . . if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to the FDA.

§ 314.3(b).

If a drug manufacturer avails itself of the CBE exception, it "need not wait for preapproval by the FDA, which is ordinarily necessary to change a label." *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. 11),* 751 F.3d 150, 161 n.23 (3d Cir. 2014) (citation and internal quotations omitted). They "need only simultaneously file a supplemental application with the FDA." *PLIVA, Inc. v. Mensing*, 564 U.S. at 614 (citing § 314.70(c)(6)).

The United States Supreme Court addressed the CBE exception in *Wyeth*. There, the Court considered whether to preempt state law claims because it was purportedly "impossible for" respondent "to comply with both the state-law duties underlying those claims and its federal labeling duties." *Wyeth*, 555 U.S. at 568 (citation omitted). The Court found that the FDA's approval of petitioner's "new drug application in 1955" and its "later approved changes in the drug's labeling" did not provide a "complete defense" to state law claims.[8] *Id.* at 558-59. As a result, the Court declined to exercise preemption, finding that the petitioner "failed to demonstrate

[8] The United States Supreme Court highlighted the following facts in considering petitioner's alleged defense.

> In 1973 and 1976, [petitioner] submitted supplemental new drug applications, which the [FDA] approved after proposing labeling changes. [Petitioner] submitted a third supplemental application in 1981 in response to a new FDA rule governing drug labels. Over the next 17 years, [petitioner] and the FDA intermittently corresponded about Phenergan's label. The most notable activity occurred in 1987, when the FDA suggested different warnings about the risk of arterial exposure, and in 1988, when [petitioner] submitted revised labeling incorporating the proposed changes. The FDA did not respond. Instead, in 1996, it requested from [petitioner] the labeling then in use and, without addressing [plaintiff's] 1988 submission, instructed it to retain verbiage in current label regarding intra-arterial injection. [] After a few further changes to the labeling not related to intra-arterial injection, the FDA approved [petitioner's] 1981 application in 1998, instructing that Phenergan's final printed label must be identical to the approved package insert. []

Wyeth, 555 U.S. at 561-62 (citations and internal quotations and brackets omitted).

[] it was impossible for it to comply with both federal and state requirements[,]" because the CBE exception "permitted [petitioner] to unilaterally strengthen its warning[.]" *Id.* at 573.

In *Bartlett,* which was decided four years after *Wyeth*, the United States Supreme Court considered "whether federal law pre-empts the New Hampshire design-defect claim under which respondent [] recovered damages from petitioner[,]" the "manufacturer of sulindac, a generic nonsteroidal anti-inflammatory drug . . . ." 570 U.S. at 475. There, the Court noted that "New Hampshire law impose[d] a duty on manufacturers to ensure that the drugs are not unreasonably unsafe, and a drug's safety is evaluated by reference to both its chemical properties and the adequacy of its warnings." *Ibid.* Further, that "[b]ecause [petitioner] was unable to change sulindac's composition as a matter of both federal law and basic chemistry, New Hampshire's design-defect cause of action effectively required [petitioner] to change sulindac's labeling to provide stronger warnings." *Ibid.*

Ultimately, the Court determined that the First Circuit's stop-selling "solution—that [petitioner] should simply have pulled sulindac from the market in order to comply with both state and federal law[,]" was unworkable, and contrary to the Court's pre-emption case law. *Id.* at 475. "[A]s th[e] Court recognized just two Terms ago in" *PLIVA, Inc.*, "federal law prohibits generic drug manufacturers from independently changing their drugs' labels" and, "[a]ccordingly, state law imposed a duty on [petitioner] *not* to comply with federal law." *Id.* at 475. In distinguishing *Barlett*, Judge Vasquez found AMAG, a brand name drug manufacturer, could have availed itself of the CBE exception. (Vazquez Op. at 11-12).

Here, AMAG argues that *Wyeth* provides that the CBE is "an exception to the general rule that label changes without prior approval are not permitted" (AMAG's Br. at 41) (internal

quotations omitted)) yet fails to show that the CBE was unavailable to it. Instead, AMAG directs the Court to a distinction within the CFR concerning label changes.

The CFR distinguish between "major changes" that "require[] supplement[al] submission and approval" and "moderate changes" (the CBE exception), which are "[c]hanges requiring supplement[al] submission at least 30 days prior to distribution of the drug product made using the change . . . ." 21 C.F.R. § 314.70(b), (c). Major changes on the other hand include "[a]ny change to the information required by § 201.57(a) . . . ." § 314.70(b)(v)(C). AMAG points to the "Indications and usage" provision, which is "[a] concise statement of each of the product's indications" (§ 201.57(a)(6)), to argue that Plaintiffs here seek a major change.

AMAG relies on *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, where the Sixth Circuit determined that "changing the dosage level of the active ingredient" of a drug constitutes a "major change[]" as it concerned a change "in the qualitative or quantitative formulation of the drug product . . . ." 808 F.3d 281, 298 (6th Cir. 2015) (citation and internal quotations omitted) (emphasis removed). AMAG further asserts that *Yates* applied *Bartlett's* "stop-selling rationale to brand-name drugs" (AMAG's Br. at 43) (internal quotations omitted) (emphasis removed)). However, the drug formulation changes at issue in *Yates* differ from the modifications or deletions to Makena's label here. Moreover, courts in this District have found that *Yates* misapplied *Bartlett*. *See Gaetano v. Gilead Scis., Inc.*, 529 F. Supp. 3d 333, 343-44 (D.N.J. 2021). Plaintiffs also do not seek "additional safety warnings" or further information, but the deletion of alleged misrepresentations. *See* (AMAG's Br. at 41-42; Pls.' Br. at 20-21).

AMAG next contends that Plaintiffs' proposed deletion of "misrepresentations about the efficacy of Makena" (*see* Pls.' Br. at 20) is a major change that does not fall under the CBE exception. (AMAG's Br. at 42-43). Plaintiffs argue that AMAG could have simply deleted one

sentence from Makena's "Indications and Usage" portion of the label (Pls.' Br. at 22), which AMAG disputes. (AMAG's Reply at 21 n.7). The Court need not determine now whether that portion of the label qualifies as a "major change[]" under 314.70(b) because even if true, this would not have prevented AMAG from utilizing the CBE exception. For example, AMAG could have used the CBE exception "[t]o add or strengthen a contraindication, warning, [or] precaution," which may have obviated Plaintiffs' claims. §314.70(c)(6)(iii)(A). It did not do so. Thus, the Court rejects AMAG's repeated assertion that the "***only*** way [it] could have complied with" state law "would have been to stop selling Makena altogether." (Reply at 22).[9]

b) Preemption of Certain Pre-and-Post March 8, 2019 Claims

The Vasquez Opinion identified "two straightforward" deficiencies in the Amended Complaint, Plaintiffs failed to allege: (1) "AMAG's knowledge pre-dating the release of the PROLONG study in March 2019[;]" and (2) when Plaintiffs "took Makena after March 2019 . . . ." (Pls.' Br. at 11; Vazquez Op. at 16-17). In arguing that deficiencies remain, AMAG contends that Plaintiffs do not sufficiently allege "newly acquired information" under 21 C.F.R. § 314.70(c)(6)(iii) (the pre-March 8, 2019 claims) and that there is "clear evidence" that the FDA "would have rejected a label change disclosing the PROLONG results" (the post-March 8, 2019 claims). (AMAG's Br. at 39-40).

[9] AMAG does not have an obligation to show that it tried to change its label pursuant to the CBE exception. As courts in this District have found. *See In re Fosamax*, 593 F. Supp. 3d at 118-19. Indeed, the phrase "would not have approved" a label change in *Wyeth* implies that a drug manufacturer may prove preemption without showing that it proposed or pursued a label change. The Court finds that *Merck* reiterated *Wyeth*'s reasoning that the availability of the CBE exception makes it such that a manufacturer "will not 'ordinarily' be able to show" an "actual conflict between state and federal law . . . ." *See also Crockett v. Luitpold Pharms., Inc.*, No. 19-276, 2020 WL 433367, at *6 (E.D. Pa. Jan. 28, 2020) ("The defense of impossibility preemption is premised on a contention that a federal regulation would have prohibited the additional warnings that the plaintiff alleges state law requires."); *Yamagata v. Reckitt Benckiser LLC*, 445 F. Supp. 3d 28, 33 (N.D. Cal. 2020) ("The preemption analysis in [*Merck*] turned on whether the FDA would have approved a change to the drug label."); *Silverstein v. Boehringer Ingelheim Pharms., Inc.*, No. 19-81188, 2020 WL 6110909, at *9 (S.D. Fla. Oct. 7, 2020) ("[Preemption] can be satisfied [under *Merck*] even if the labeling change has not been presented to, and rejected by, the FDA.").

The CFR require drug manufacturers to inform the FDA of "adverse drug experience information[,]" as well as "significant new information . . . that might affect the safety, effectiveness, or labeling of the drug product." 21 U.S.C. §§ 314.80(c), 314.81(b)(2)(i). A drug manufacturer may change its label by: (1) "seek[ing] advance permission form the FDA through a Prior Approval Supplement Application[;]" or (2) "chang[ing] a label immediately and unilaterally through a [CBE application] to reflect newly acquired information about evidence of a casual association between the drug and a risk of harm." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 593 F. Supp. 3d at 105-06 (citations and internal quotations omitted). "Whatever method a manufacturer chooses, it must meet the causal thresholds described above, and significantly, the FDA retains authority to reject even a CBE amendment . . . ." *Id.* 106 (citations omitted).

"Because of the availability of the CBE process, a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." *Id.* at 106 (citations and internal quotations omitted). However, the FDA "will not approve a warning simply out of an abundance of caution whenever a manufacturer posits an association between a drug and an adverse event." *Id.* at 106. That is because the FDA "has long recognized, "exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug." *Id.* at 106 (citation and internal quotations and brackets omitted). Here, certain claims are preempted.

i. The Pre-March 8, 2019 Claims

Preliminarily, the Court clarifies that Judge Vazquez did not specifically find dismissal appropriate if Plaintiffs failed to allege that AMAG could have changed its label without prior FDA approval. (*Id.* at 39, 44). Rather, Judge Vazquez noted that "[s]everal courts have" so held,

including in the First Circuit (*In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34 (1st Cir. 2015)). (Vazquez Op. at 14). The holding in *Celexa*, however, "is far from established law." *In re Proton-Pump Inhibitor Prods. Liab. Litig.*, No. 17-2789, 2022 WL 18999830, at *25 (D.N.J. July 5, 2022). Indeed, a court in this District declined to follow *Celexa* based upon the distinction between the obstacle preemption rule discussed therein and the impossibility preemption rule under consideration here. *Gaetano*, 529 F. Supp. 3d at 346, n.7.

Substantively, Judge Vazquez found that the only "newly acquired information" in the Amended Complaint consisted of a single allegation that AMAG "knew far earlier than finalization of the PROLONG [s]tudy that Makena was ineffective" based on "information and belief[.]" (Vazquez Op. at 15-16) (citation omitted). The court also found that Plaintiffs did not show how AMAG could have obtained the "final results of a double blinded, placebo-controlled clinical trial" before "all data was collected and analyzed." (*Id.* at 16) (citation and internal quotations omitted). In granting the initial motion to dismiss, Judge Vazquez held that Plaintiffs failed to meet the standard for fraud claims pled on information and belief, and dismissed the consumer fraud claims that accrued before March 8, 2019. (*Ibid.*).

Here, the Second Amended Complaint's sole allegation pled "[o]n information and belief" relates to Plaintiffs' class allegations (*see* SAC ¶ 183) that are not based on consumer fraud. Consequently, the information and belief test (*see* Vasquez Op. at 16), does not apply; and the Court analyzes the Second Amended Complaint to determine whether Plaintiffs sufficiently allege that AMAG obtained "newly acquired information" to avail itself of the CBE exception.

Plaintiffs allege that AMAG "knew far earlier than public release of the" PROLONG study that "Makena was ineffective." (SAC ¶ 112). Further that AMAG was listed as a "Collaborator" in 2014 and a "Sponsor" in 2016 of the PROLONG study, which provided it access to data, records,

clinical research, and "evidence related to the safety and effectiveness of" Makena. (*Id.* ¶¶ 113, 119-21, 123-24, 126-27). Also, that several AMAG employees "had access" to "data from the PROLONG [study] at any time during the period in which the study was being conducted." (Pls.' Br. at 26-27) (citing SAC ¶ 148).

In 2019, the United States Supreme Court reiterated its prior ruling in *Wyeth* that the "FDA's CBE regulation [] permits drug manufacturers to change a label to reflect newly acquired information . . . without prior approval from the FDA." *Merck Sharp & Dohme Corp.*, 139 S. Ct. at 1679 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)). To that end, courts decline to find consumer protection law claims preempted by federal law if "newly acquired information" is available. *In re Avandia Mktg., Sales & Prod. Liab. Litig.*, 945 F.3d 749, 760 (3d Cir. 2019).

In considering a motion to dismiss under 12(b)(6), preemption must be "manifest in the complaint itself" and, even then, courts must "tread warily" before dismissing a complaint as preempted. *Gaetano*, 529 F. Supp. 3d at 348 (citations and internal quotations omitted). The Court must also assume the truth of the allegations to determine whether Plaintiffs pled plausible causes of action. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009) (citation omitted).

Here, Plaintiffs' allegations that AMAG had access to the PROLONG study's information as a Sponsor and Collaborator are sufficient to deny preempted as to the pre-March 8, 2019 claims. For similar reasons, whether AMAG had access to the PROLONG study's information given that the "study was [a] randomized, double-blinded, placebo-controlled clinical trial" (*see* SAC ¶ 144), is a question to be established or refuted through discovery. *See Gaetano*, 529 F. Supp. 3d at 349 (finding preemption was not "manifest from the face of the Complaint" because whether defendant "knew through its studies that otherwise healthy individuals were experiencing adverse kidney events" before a date certain "must be developed in discovery."). Similarly, the Court does not

need to decide today whether the PROLONG study's information in fact "rises to the level of newly acquired information." (AMAG's Br. at 45) (internal quotations omitted). The case law cited by AMAG does not alter this finding.

In *Mahnke v. Bayer Corp.*, the court considered whether "newly acquired information" had to "have been available to [defendant] after the FDA approved the relevant label on August 19, 2020, but before Plaintiff last used [the drug] on May 1, 2015." No. 19-7271, 2020 WL 2048622 at *3 (C.D. Cal. Mar. 10, 2020). The time frame was necessary to determine whether there was "a casual association between [the drug] and a clinically significant adverse reaction." *Id.* (citations omitted). The plaintiff argued that certain articles qualified as newly acquired information despite being "published after Plaintiff's last exposure" to the drug because "they draw on information that pre-dates May 2015." *Id.* Also, that a "briefing document prepared" in 2017 qualified because it "could have been used by" defendant "to invoke the CBE exception." *Id.* The court found neither material qualified as "newly acquired information" because they fell outside the relevant period. *Id.* at *4. Here, Plaintiffs allege AMAG had access to the purported "newly acquired information" before, not after, the PROLONG study's public release. Thus, *Mahnke* is inapposite.

Moreover, courts in this District have found discovery to be a prerequisite to determining whether information obtained from studies qualifies as "newly acquired information[;]" and that this question should not be answered on a Rule 12(b)(6) motion. *See Gaetano*, 529 F. Supp. 3d at 348-39; *see also In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016) ("[A] motion under Rule 12(c) for judgment on the pleadings is a more appropriate vehicle for dismissing cases on preemption grounds, instead of a motion under Rule 12(b)(6) . . . .") (citations omitted); *In re Fosamax (Alendronate Sodium) Products Liability Litig.*, 593 F. Supp. 3d 96, 140 (D.N.J. 2022) (the "question of whether newly acquired information exists is fact-intensive" when

deciding preemption on summary judgment) (citations and internal quotations and brackets omitted).

AMAG relies on equally distinguishable case law that involves securities class actions brought under the Securities Exchange Act of 1934; and are based on a "core operations" theory, which is unrelated to the allegations here. *See Markette v. XOMA Corp.*, No. 15-3425, 2017 WL 4310759, at *12 (N.D. Cal. Sept. 28, 2017) ("Plaintiff's allegations [] do not sufficiently plead scienter on a core operations theory."); *In re Vical Inc. Sec. Litig.*, No. 13-2628, 2015 WL 1013827, at *6 (S.D. Cal. Mar. 9, 2015) (Complaint failed "to allege any facts that would support an inference that Defendants knew" certain "assumptions were faulty at the time they made the projections"); *Anderson v. Peregrine Pharms., Inc.*, No. 12-1647, 2013 WL 4780059, at *12 (C.D. Cal. Aug. 23, 2013) ("The core operations doctrine cannot be used to infer that any Defendant had any" knowledge "that the data in the double-blind study was unverified . . . .").

AMAG next cites *Gayle v. Pfizer Inc.,* where, on a motion for judgment on the pleadings, the court considered whether "6,000 adverse event reports relating to diabetes sent from [defendant] to the FDA constitute newly acquired information." 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020) (internal quotations omitted). The court found that the reports did not constitute "newly acquired information" in part because defendant was already required to submit the information to the FDA. *Id. Gayle* is inapposite due to defendant's preexisting disclosure obligation in that case. AMAG's next cited cases are similarly unpersuasive.

In considering post-trial motions, the court in *Knight v. Boehringer Ingelheim Pharms., Inc.*, determined that a published article was not "newly acquired information" that was finalized *after* plaintiff's underlying adverse gastrointestinal bleed reaction; that contained information of which the FDA was already aware; and did not "reveal risks of a different type or greater severity

or frequency."[10] 984 F.3d 329, 338-39 (4th Cir. 2021) (citation and internal quotations and ellipses omitted) (emphasis added).

McGrath v. Bayer Healthcare Pharm. Inc. concerned in relevant part failure to warn claims alleged in response to plaintiff's purported "injuries sustained as a result of exposure to Magnevist, an FDA-approved gadolinium-based contrast agent" that is "administered to patients to enhance the quality of MRIs." 393 F. Supp. 3d 161, 164 (E.D.N.Y. 2019). Plaintiff "claim[ed] that prior to receiving Magnevist she was never warned about the risks of gadolinium retention for patients with normal renal function or advised of alternative options." *Id.* at 164 (internal quotations omitted). Defendant sought dismissal in part based on the "FDA's regulatory scheme governing pharmaceutical labeling." *Id.* at 165.

The court found that "[r]eports and studies" were not "newly acquired information[,]" and that "to draw the reasonable inference that [defendant] could have unilaterally amended the Magnevist label in compliance with the FDA's CBE regulation, the Complaint must plead more than the mere possibility that Magnevist caused Plaintiff's … injuries." *Id.* at 168-69. Further, that "the more recent scientific studies in Plaintiff's Second Amended Complaint[] do not compel a contrary conclusion" because "not only were these studies *published after* Plaintiff received injections of Magnevist, but" they "do not plausibly allege the requisite causal connection under the FDA's regulatory scheme." *Id.* at 168 (emphasis added).

As explained herein, *Knight* and *McGrath* are inapposite. Plaintiffs do not seek to rely on information generated post-injury. *See* (SAC ¶ 146) (AMAG's access to information from the

[10] By way of background, "Boehringer Ingelheim Pharmaceuticals, Inc., developed a drug called Pradaxa to help reduce the risk of stroke." 984 F.3d at 332. "The FDA approved the drug and its label." *Ibid.* "After taking this drug for over a year, [plaintiff] suffered a gastrointestinal bleed." *Ibid.* "She then developed other complications and eventually died." *Ibid.* "Her children, Claude Knight and Claudia Stevens, sued [defendant] asserting a variety of state-law claims alleging [defendant] failed to adequately warn about the risks associated with taking Pradaxa." *Ibid.*

PROLONG allowed it to know far earlier "that Makena does not work."). Indeed, Plaintiffs limit their allegations to only those claims arising before March 8, 2019 (*see* SAC ¶¶ 112-13, 119-21, 123-24, 126-27), which are sufficient to deny preemption. *See In re Taxotere (Docetaxel) Prods. Liab. Litig.*, No. 16-2740, 2022 WL 3042639, at *9 (E.D. La. Aug. 2, 2022) (Information "that came available after" a plaintiff took a particular drug "cannot constitute newly acquired information."); *Pfaff*, *v. Merck & Co.*, 627 F. Supp. 3d 134, 146 (E.D.N.Y. 2022) ("[A]ny newly acquired information must be from before March 2012, and after Merck submitted its CBE supplement in July 2010."). Accordingly, *Knight* and *McGrath* are not controlling precedent.

Finally, AMAG disputes Plaintiffs' allegations that it learned Makena "was ineffective" directly from patients. (*Id.* ¶¶ 135-36). The Court must accept as true Plaintiffs' allegations. *Sheridan*, 609 F.3d at 262 n.27. Thus, whether "0.408% of women who took Makena in 2014 reported experiencing a premature birth" is sufficient or dispositive will bear itself out in discovery. (AMAG's Br. at 48) (emphasis removed). Therefore, Plaintiffs' collaborator and sponsor allegations are sufficient to overcome preemption at this stage. Accordingly, AMAG's motion to dismiss is denied for claims arising before March 8, 2019.

ii. The Preempted Post-March 8, 2019 Claims

Judge Vazquez found Plaintiffs' previous Amended Complaint deficient because Plaintiffs failed to allege when Plaintiffs "took Makena after March 2019 . . . ." (Pls.' Br. at 11; *see also* Vazquez Op. at 16-17). Indeed, the only dates alleged therein concerned the class period that purportedly ran from "January 2014 to the present." (Vazquez Op. at 17) (internal quotations omitted). Therefore, Judge Vazquez dismissed Plaintiffs' claims arising after March 8, 2019, because Plaintiffs "failed to allege the specific date on which they were prescribed, injected with, and purchased Makena." (*Id.*) (citation omitted).

Here, AMAG argues that claims concerning Plaintiffs Jasmin Amaro ("Amaro"), Gloria Uribe ("Uribe"), Carolyn Gill ("Gill"), Mary Jo Barnes ("Barnes"), Luz Vargas ("Vargas"), Jennifer Maltese ("Maltese"), and Lisa Brady ("Brady") are preempted because the Second Amended Complaint does not allege that these Plaintiffs "were prescribed, injected with, and purchased Makena" after March 8, 2019. *See* (Vazquez Op. at 17) (internal quotations omitted); (*see also, gen.,* SAC) (AMAG's Br. at 49 n.23) (emphasis removed). The Court agrees.

Plaintiffs do not specifically allege the dates that Amaro, Uribe, Gill, Barnes, Vargas, Maltese, and Brady were "prescribed, injected with, or purchased Makena" to assist the Court in determining "which, if any, of Plaintiffs' claims survive" the court's prior "finding that claims arising prior to March 8, 2019, are preempted." (Vazquez Op. at 17). The Second Amended Complaint also newly names Uribe and Vargas yet alleges only pre-March 8, 2019 dates. Indeed, Plaintiffs identify only Marina Gomez ("Gomez"), Rebecca Torres ("Torres"), Brittany Bonds ("Bonds"), Teresa Faughnan ("Faughnan"), and Ebony Odommorris ("Odommorris") as receiving, being injected with, and/or purchasing Makena after March 8, 2019. (Pls.' Br. at 11 n.1).[11] Because Plaintiffs did not specifically allege the dates that Amaro, Uribe, Gill, Barnes, Vargas, Maltese, and Brady were prescribed, injected with, or purchased Makena, the Court dismisses the post-March 8, 2019 claims without prejudice as to these Plaintiffs only; and denies the motion to dismiss as to Maher, Gomez, Torres, Bonds, Faughnan, and Odommorris. (*See* SAC ¶¶ 3, 10, 13, 27, 31, 36).

iii. The Remaining Post-March 8, 2019 Claims

AMAG argues that Plaintiffs' post March 2019 claims are preempted because "there is now clear evidence that the FDA would have rejected" AMAG "chang[ing] Makena's label

[11] Plaintiff also alleges Rachel Maher ("Maher") was treated with Makena from April to July 2019. (SAC § 3).

through the CBE process based on newly acquired information . . . ." (AMAG's Br. at 50) (internal quotations omitted). Specifically, that the FDA's October 5, 2020 letter rejecting AMAG's proposed "supplement for labeling revisions" (*see* Ex. J (ECF No. 79-11) (the "Complete Response Letter") to Marc A. Marinaccio's August 23, 2021 Declaration (ECF No. 79-2) (the "Marinaccio Decl.")), is "clear evidence" that the FDA would have rejected AMAG's proposed label change. (AMAG's Br. at 51-52). The Court disagrees; and denies preemption as to the post March 8, 2019 claims concerning Maher, Gomez, Torres, Bonds, Faughnan, and Odommorris.

Citing *Merck Sharp & Dohme Corp.*, 139 S. Ct. 1668, Judge Vazquez stated that:

> To show that federal law prohibited [AMAG] from adding a warning that would satisfy state law, AMAG must show (1) it fully informed the FDA of the justifications for the warning required by state law by submitting all material information to the FDA, and (2) the FDA informed [AMAG] that the FDA would not approve a change to the drug's label to include the warning.

(Vazquez Op. at 12-13) (internal quotations omitted). The court further noted that AMAG must support this with "necessary evidence." (*Id.* at 13) (citation and internal quotations omitted).

In *Merck*, the U.S. Supreme Court held that "clear evidence that the FDA would not have approved a change to the drug's label pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." *Id.* at 1672 (citing *Wyeth*, 555 U.S. at 571) (internal quotations omitted). The court explained that "clear evidence is evidence that . . . the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Ibid.* (internal quotations omitted).

While AMAG contends that it "fully informed the FDA of the results of the PROLONG study at the time of their release in March 2019" (*see* AMAG's Br. at 51), whether the FDA

informed AMAG that it would not approve a label change is disputed. Plaintiffs contend that the Complete Response Letter fails to meet the second prong. In support, they cite *In re Avandia Mktg.*, wherein the FDA sent defendant a letter stating that it required supplemental information to decide whether to approve a label change. 945 F.3d at 759-60; *see also* (Pls.' Br. at 24-25). There, the court found the letter insufficient because "[a]t most, the Letter indicates that it is *possible* that the FDA could have rejected the label change *after* receiving the various data and information it requested from GSK, but as the Supreme Court has reiterated, the possibility of impossibility is not enough." *In re Avandia Mktg.*, 945 F.3d at 760 (citation and internal quotations and brackets omitted). Thus, the state consumer protection claims were not preempted. *Id.* at 761.

Here, Plaintiffs argue that the Complete Response Letter is lacking because it is an informal rejection that was not issued via the FDA's "congressionally-mandated authority" or "congressionally delegated authority[,]" which AMAG disputes. (*See* Pls.' Br. at 24; Reply at 17). *Merck* recognized that complete warning response letters qualify as congressionally delegated authority. *Merck*, 139 S. Ct. at 1679 (citing 21 C.F.R. §§ 314.110(a), 314.125(a)). Nonetheless, the Court finds that the Complete Response Letter does not meet the second prong because it does not serve as the FDA's express rejection of the proposed label change.

The FDA issued the Complete Response Letter following AMAG's supplemental new drug application ("sNDA") request (*see* AMAG's Br. at 51), rather than a supplemental application for AMAG to avail itself of the CBE exception. *See Wyeth*, 555 U.S. at 571. AMAG, however, requests that the Court treat the FDA's response to the sNDA (Complete Response Letter) as a rejection of AMAG's unilateral label change pursuant to the CBE exception. Because AMAG: (i) did not submit a supplement to avail itself of the CBE exception; (ii) proffered nothing to show that it attempted to utilize the CBE exception; and (iii) opted for a sNDA instead of the CBE

exception, the Court declines. Thus, AMAG's contention that the Seventh Circuit deems such correspondence to be "clear evidence" (Reply at 17 n.6), is inapposite. Equally unpersuasive is AMAG's citation to numerous cases in sister jurisdictions for the same proposition. (*Id.* at 19-20).

The cases cited are also unpersuasive because they reinforce the Court's reasoning that the "clear evidence" analysis is triggered when a drug manufacturer availed itself of the CBE exception (AMAG's Br. at 52-53), which AMAG did not do. Further, courts in this District allow such issues to proceed beyond a motion to dismiss. *See Gremo v. Bayer Corp.*, 469 F. Supp. 3d 240, 253-54 (D.N.J. 2020) ("[I]mpossibility pre-emption is a demanding defense" and "[e]ven though a judge . . . must decide the pre-emption question," that "question is not properly before the Court to answer at this time.") (citation and internal quotations omitted). Accordingly, Plaintiffs' post-March 8, 2019 claims as to Maher, Gomez, Torres, Bonds, Faughnan, and Odommorris may proceed.

2. Counts Four and Seven Are Dismissed as Abandoned

AMAG argues Counts Four and Seven should be dismissed for the same reason that Plaintiffs' post-March 8, 2019 claims are preempted. (AMAG's Br. at 49 n.23). The Court disagrees, but dismisses the claims as abandoned.

Counts Four and Seven rely on allegations related to Brady and Gill. (SAC ¶¶ 220-26, 48-54). While the Court dismissed Counts Four and Seven to the extent they arose after March 8, 2019, it dismisses the claims in their entirety because Plaintiffs failed to dispute or respond to AMAG's argument in its opening brief. *See Cabrera v. Nazor*, No. 23-2745, 2024 WL 310523, at *5 (D.N.J. Jan. 25, 2024) (citation omitted), *aff'd as modified*, 813 F.App'x 780 (3d Cir. 2020)). To be sure, the Court finds no independent basis to maintain these claims. Thus, in failing to dispute that Counts Four and Seven should be dismissed as to Brady and Gill on preemption

grounds, Counts Four and Five are dismissed as abandoned. *Depalma v. N.J. Turnpike Auth.*, No. 20-3210, 2020 WL 6689800, at *7 (D.N.J. Nov. 13, 2020). Though some courts dismiss abandoned claims with prejudice (*see Sevajian v. Castro*, No. 20-1591, 2022 WL 17733675, at *3 n.1 (D.N.J. Dec. 6, 2022)), dismissal here is without prejudice.

3. The Learned Intermediary Doctrine Does Not Preclude the Claims

AMAG argues Counts One to Seven are "barred by the learned intermediary doctrine." (AMAG's Br. at 61). In sum, the doctrine does not preclude Plaintiffs' claims.[12]

The New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.*, "incorporates the learned intermediary doctrine, by which a pharmaceutical manufacturer generally fulfills its duty to warn the ultimate user of its prescription drug when it supplies physicians with adequate information about a drug's dangerous propensities." *Vicente v. DePay Synthes Cos.,* 570 F. Supp. 3d 232, 245 (D.N.J. 2021) (citation and internal quotations and ellipses omitted). Courts, however, "recognize[] an exception to that doctrine when a pharmaceutical company has advertised its drug directly to the consuming public." *Id.* at 245. (citation and internal quotations omitted). Because such an exception may apply, the Court does not find that the doctrine bars the claims at this stage.

Next, AMAG asserts that Plaintiffs' claims sound in a failure to warn and are not based on AMAG's alleged misrepresentations and/or omissions (*see* SAC ¶¶ 177, 181), which in effect favors Plaintiffs. Indeed, the causes of actions are distinguishable. New Jersey's CFA claim is based in part on a defendant's "misrepresentation[s]," "concealment," and/or "omission[s][,]" "in connection with the sale or advertisement of any merchandise . . . ." N.J.S.A. 56:8-2. A failure to warn claim concerns a duty to warn or instruct of risk or danger and safe use of a product that a defendant breached. *Gaetano*, 529 F. Supp. 3d at 344 (citation omitted). The Second Amended

[12] Though Counts Four and Seven are dismissed, the learned intermediary doctrine does not preclude these claims.

Complaint does not reference duty, breach, or a failure to warn. Accordingly, the claim does not sound in a failure to warn. (*See, gen.,* SAC).

Rather, "Plaintiffs assert that their doctors prescribed Makena to them based on AMAG's false representations concerning its effectiveness." (Pls.' Br. at 60; *see also* SAC ¶¶ 90-92). Further, "had their doctors known that the drug was completely ineffective and unsafe, Makena would not have been prescribed" and Plaintiffs would not have paid for it. (Pls.' Br. at 60). To that end, courts "recognize that a physician's prescription under such circumstances does not break the causal chain. *In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.,* No. 5-1699, 2007 WL 2028408, *4–5 (N.D. Cal. July 10, 2007) ("SAC alleges that defendants deceived the physicians, as well as the consumers and third-party payors . . . .") (emphasis removed). Accordingly, AMAG's learned intermediary doctrine argument fails at this stage of the litigation.

4. The Safe Harbor Provisions Do Not Bar Plaintiffs' Claims

AMAG contends that Counts One to Three and Count Six are precluded "by statutory or precedential safe harbors that" do "not cover misrepresentations regarding the sale of regulated prescription drugs like Makena that are marketed in compliance with FDA requirements." (AMAG's Br. at 56) (internal quotations omitted). The Court disagrees.

a) <u>The New Jersey CFA Claim (Count One)</u>

AMAG concedes that the CFA "does not include an express statutory safe harbor" provision (AMAG's Br. at 58), but nevertheless asserts that "New Jersey courts have declined to apply" safe harbor "to activities that are comprehensively regulated by federal or state agencies, like the direct-to-consumer marketing of prescription drugs." (*Ibid.*). Specifically, AMAG cites *N.J. Citizen Action v. Schering-Plough Corp.*, which concerned a CFA claim brought by consumers against a pharmaceutical company concerning the company's advertising and

marketing. 367 N.J. Super. 8 (App. Div. 2003). There, the New Jersey Appellate Division found defendant's statements such as "you can lead a normal nearly symptom-free life again" are "merely expressions in the nature of puffery" that "are not transformed into a guarantee of universal and complete effectiveness and thus are not statements of fact actionable under the CFA." *Id.* at 13-14 (internal quotations and ellipses omitted). Relying on New Jersey Supreme Court precedent, the court stated that "[t]o constitute consumer fraud the business practice in question must be misleading and stand outside the norm of reasonable business practice in that it will victimize the average consumer." *Id.* at 13 (citation and internal quotations, brackets, and ellipses omitted). Moreover, that the New Jersey Supreme Court "has also recognized that there is indeed a distinction between misrepresentations of fact actionable under the CFA and mere puffing about a product or a company that will not support relief." *Id.* at 13 (citation omitted).

Here, AMAG does not contend that its statements are "non-actionable puffery" but rather focuses on the court's finding that pharmaceutical products "remain subject to the strict regulation of the FDA" under 21 C.F.R. §§ 202.1, 352, and that "the wording of the ads, to the extent that it is subject to FDA oversight," are therefore "not actionable" under the CFA. *N.J. Citizen Action*, 367 N.J. Super. at 14 (citation omitted). Plaintiffs' Second Amended Complaint contains allegations of misrepresentations of fact (*see* Pls.' Br. at 38 (citing SAC ¶¶ 1, 143-65, 173-81)), which are different in kind than the "puffery" statements addressed in *N.J. Citizen Action*. Nonetheless, *N.J. Citizen Action* does not support AMAG's contention that its holding creates a safe harbor to preempt Plaintiffs' claim. Indeed, AMAG cites no authority so providing.[13]

[13] In reviewing the relevant case law, the Court identified several pharmaceutical matters where courts did not find, as AMAG seeks here, that *N.J. Citizen Action* precludes a CFA claim. *See Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 503-04 (D.N.J. 2006); *Gray v. Bayer Corp.*, No. 8-4716, 2009 WL 1617930, at *3 (D.N.J. June 9, 2009); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 530-31 (D.N.J. 2011); and *Hoffman v. Nutraceutical Corp.*, No. 12-5803, 2013 WL 2650611, at *2 (D.N.J. June 10, 2013).

Next, AMAG's proposes that by not amending the CFA, the Legislature's silence equates to a "clear[] [] agreement that prescription drugs and other highly-regulated products or services are not actionable under the NJCFA[.]" (Reply at 30 n.15). The Court finds no basis in fact or law to support such a view. The cases cited in support are also distinguishable.

Daaleman v. Elizabethtown Gas Co. concerned a public utility and not a pharmaceutical company. 77 N.J. 267 (1978). Irrespective of whether the FDA could be considered a public utility (which AMAG does not argue that it is), the New Jersey Supreme Court has held that *Daaleman* "does not stand for the bright-line proposition that a regulated practice is . . . automatically exempt from" the CFA "based solely on the number of administrative agencies having regulatory justification over the practice." *Lemelledo v. Benefit Mgmt. Corp.*, 150 N.J. 255, 267 (1997) (citing *Daaleman,* 77 N.J. at 274) (Pashman, J., concurring).

Lemelledo concerns a class action brought against a commercial lender for extra charges added to a loan. There, the issue was whether an alternative regulatory scheme by the Department of Banking and Insurance automatically eliminated the applicability of the CFA. The court found that a direct conflict between the schemes would be required to conclude that the Legislature did not intend for the CFA to apply, which is factually distinguishable from the matter at bar. *Id.* at 270. Here, AMAG does not identify a regulation or statute in conflict.

Marcedo v. Dello Russo involved patients suing a doctor and affiliated "corporate entities he created to perform laser surgery" for CFA violations for purportedly allowing a person, "who was not fully licensed," to operate on them. 178 N.J. 340, 342 (2004). The court found that "advertisements by learned professionals in respect of the rendering of professional services are insulated from the CFA but subject to comprehensive regulation by the relevant regulatory bodies and to any common-law remedies that otherwise may apply." *Id.* at 346. This aligns with New

Jersey Supreme Court precedent recognizing an exception to CFA liability for learned professionals. *See Lee v. First Union Nat. Bank*, 199 N.J. 251, 264 (2009) ("Certainly no one would argue that a member of any of the learned professions is subject to the provisions of the Consumer Fraud Act despite the fact that he renders 'services' to the public.") (citation omitted).

Here, Plaintiffs' allegations are outside the context of "learned professionals" and fall more squarely into the category of consumerism through Plaintiffs' use of AMAG's pharmaceuticals. Consequently, *Marcedo* is unpersuasive. Therefore, because Plaintiffs' allegations fall within the CFA's provisions, the motion to dismiss Count One on the safe harbor defense is denied.

b) The California Claims (Counts Two and Three)

AMAG contends California's safe harbor doctrine bars Plaintiffs' UCL and CLRA claims based on the approval of Makena and its related statements under "FDA regulations applicable to the marketing of Makena for its approved indication." (AMAG's Br. at 60). The Court disagrees.

The UCL and CLRA, under which Plaintiff's claims are brought, prohibit unlawful, unfair, or fraudulent business practices. *See* Cal. Bus. & Prof. Code § 17200; Cal Civ. Code § 1770. Like the New Jersey CFA, neither the California UCL nor the CLRA include an express statutory safe harbor provision. "In California, unfair competition claims are subject to the safe harbor doctrine, which precludes plaintiffs from bringing claims based on actions the Legislature permits." *Ebner v. Fresh, Inc.,* 838 F.3d 958, 963 (9th Cir. 2016) (citation and internal quotations omitted). As a result, a "plaintiff may [] not plead around an absolute bar to relief simply by recasting the cause of action as one for unfair competition." *Cel-Tech Communications, Inc., v. Los Angeles Cellular Telephone Co.,* 20 Cal. 4th 163, 182 (1999) (citation and internal quotations omitted).

"The rule does not, however, prohibit an action under the unfair competition law merely because some other statute on the subject does not, itself, provide for the action or prohibit the

challenged conduct." *Id.* at 182-83. "To forestall an action under the unfair competition law, another provision must actually bar the action or clearly permit the conduct." *Id.* at 183 (internal quotations omitted); *compare Zhang v. Superior Court*, 57 Cal. 4th 364, 377 (2013) ("To forestall an action under" either the UCL or CLRA, "another provision must actually bar the action or clearly permit the conduct.") (citation and internal quotations omitted). Because the "doctrine does not immunize from liability conduct that is merely not unlawful[,]" to "fall within the safe harbor, the challenged conduct must be affirmatively permitted by statute . . . ." *Ebner,* 838 F.3d at 963.

Indeed, the California Supreme Court acknowledged that:

> There is a difference between (1) not making an activity unlawful, and (2) making that activity lawful[.] Acts that the Legislature has determined to be lawful may not form the basis for an action under the unfair competition law, but acts may, if otherwise unfair, be challenged under the unfair competition law even if the Legislature failed to proscribe them in some other provision.

Id. at 963 (citation and internal ellipses omitted).

The UCL defines "unfair competition" as "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising" and "any act prohibited by Chapter 1" of "Part 3 of Division 7 of the Business and Professional Code." Cal. Bus. & Prof. Code § 17200. Plaintiffs' allegations against AMAG's representations fall within the UCL's terms and, therefore, are not precluded by a safe harbor provision. The Court finds AMAG's argument to the contrary unpersuasive.

AMAG cites *Alvarez v. Chevron Corp.*, wherein the court provided safe harbor protection because "California law unequivocally permit[ted] Defendants" to create specific requirements for retail gasoline dispensing, which may not be trumped by the general provisions of the law (the

UCL and CLRA claims). 656 F.3d 925, 933-34 (9th Cir. 2011) (citations and internal quotations and brackets omitted). This is distinguishable from the facts here.

AMAG also cites *Ebner v. Fresh Inc.*,[14] wherein the court afforded safe harbor protection to defendant's packaging and labeling of a cosmetic product because state and federal law required the kind of labeling and packaging utilized, thereby precluding the UCL and CLRA claims. No. 13-477, 2013 WL 9760035, at *4-6. (C.D. Cal. Sept. 11, 2013). Like *Alvarez*, *Ebner* is factually distinguishable because Makena is not a cosmetic product and Plaintiffs' causes of action involve AMAG's marketing and alleged misrepresentations rather than its actual labeling and packaging. Moreover, courts that have applied *Ebner* have done so related to the design of packaging and labeling of net weight (*see Hawkins v. UGI Corp.*, No. 14-8461, 2016 WL 2595990, at *3 n.3 (C.D. Cal. May 4, 2016)), neither of which are at issue here.

Similarly, in *Pom Wonderful LLC v. Coca Cola Co.*, No. 8-6237, 2013 WL 543361, at *5 (C.D. Cal. Feb. 13, 2013), the court reviewed whether California's safe-harbor doctrine insulated Defendant from Plaintiff's state claims under California's UCL and False Advertising Law ("FAL") claims. Plaintiff, a producer of pomegranate juice blends, alleged that Defendant, a producer of similar products, violated state law by misleadingly naming and labeling its blend based on the percentage of juice content. *Id.* at *1. The court held the FDA authorized the label under the Food, Drug, and Cometic Act, thus preempting the claims. *Id.* at *5. Put simply, to trigger safe harbor protection, another provision must bar the action or clearly permit the conduct.

Here, AMAG points to neither a specific FDA regulation that it complied with nor a federal or state law that permitted its alleged misleading marketing or statements. Plaintiffs allege that AMAG did not avail itself of the CBE exception. Consequently, even if the FDA believed at the

[14] An unreported case published three years before *Ebner,* 838 F.3d 958.

time that AMAG's statements were not misrepresentations and took no issue with its marketing, Plaintiffs allege that AMAG did not submit a supplement as part of the CBE exception and opted to submit the sNDA. Application of a safe harbor is not appropriate under these circumstances.

Moreover, granting the motion would be inappropriate because it "is not clear based on the face of the" Second Amended Complaint that AMAG "is entitled to the protection of the safe harbor . . . ." *McMillan v. Lowe's Home Ctrs., LLC*, No. 15-695, 2016 WL 2346941, at *7 (E.D. Cal. May 4, 2016). Accordingly, Plaintiffs' California claims are not precluded.

c) The New York Business Law Claim (Count Six)

"The New York General Business Law safe harbors are co-extensive with the Court's preemption analysis, and thus any claims that survived … preemption are not felled by the statutes' safe harbors." *Wedra v. Cree, Inc.*, No. 19-3162, 2020 WL 1322887, at *6 (S.D.N.Y. Mar. 20, 2020). Unlike the California and New Jersey claims, Plaintiffs' New York Business Law claim is subject to a legislative "safe harbor" provision. Nevertheless, the motion is denied on this defense.

In cases involving alleged "[d]eceptive acts or practices in the conduct of any business," the New York Business Law provides "a complete defense" to the "act or practice" if it is "subject to and complies with the rules and regulations of . . . any . . . agency of the United States . . . ." N.Y. Gen Bus § 349(d). However, where, like here, the parties "dispute" defendant's "compliance" with the rules and regulations at issue, safe harbors are not applied on a motion to dismiss. *See Sadigh v. Educ. Credit Mgmt. Corp.*, No. 22-298, 2023 WL 6389773, at *4 (E.D.N.Y. Sept. 30, 2023); *Gwinn v. Laird Superfood, Inc.*, 643 F. Supp. 3d 450, 457 (S.D.N.Y. 2022).

AMAG "does not point to any facts appearing on the face of the" Second Amended Complaint "that supports its affirmative defense: that the Product's packaging complied with"

federal law and "implementing regulations." *Bardsley v. Nonni's Foods, LLC*, No. 20-2979, 2022 WL 814034, at *12 (S.D.N.Y. Mar. 16, 2022). Accordingly, Count Six is not precluded.

5. The Second Amended Complaint Initially Satisfies Rule 9(b)

Initially, the Court addresses AMAG's argument that Plaintiffs fail to allege with particularly their allegations "regarding compounded 17P." (AMAG's Br. at 65). Plaintiffs do not specifically address this argument. And only reference such allegations with respect to the RICO claim. Therefore, the Court strikes the 17P allegations in support of the California, New Jersey, and New York law claims (*see* SAC ¶¶ 193, 201, 213, 232, 242) as "immaterial" under Federal Rule of Civil Procedure 12(f)(1). *See Crimone v. McCabe Weisberg & Conway, P.C.*, 737 F.App'x 107, 111 (3d Cir. 2018) ("[W]e agree with the District Court that the portions stricken were at best immaterial because they had no bearing on the merits of" the claims) (citation and internal quotations omitted). The Court now reviews whether the pleading meets Rule 9(b).

In citing *In re Craftmatic Securities Litig.*, 890 F.2d 628, 645 (3d Cir. 1989), Plaintiffs suggest that Rule 9(b)'s heightened pleading requirements should be relaxed. (Pls.' Br. at 61). While *Craftmatic* is factually and legally distinguishable and, therefore, inapplicable, the Rule will not be relaxed because the face of the pleading satisfies Federal Rule of Civil Procedure 9(b). When "alleging [a] fraud" claim, "a party must state with particularity the circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b). That means a complaint satisfies "Rule 9(b)'s particularly requirement" if it "alleges[] all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue." *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019) (citations and internal quotations omitted). The pleading sufficiently does so here. (*See* SAC ¶¶ 1, 60-78, 143-50).

The Court also rejects AMAG's suggestion that Plaintiffs must "show" today that they "viewed the specific statements at issue" and that "that occurred before or after her decision to purchase Makena . . . ." (AMAG's Br. at 65 n.32). That is not so. First, Plaintiffs do not need to establish at this stage that they viewed the statements at issue. *See Ashcroft*, 556 U.S. at 678 ("A claim has facial plausibility" to defeat a motion to dismiss "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.") (citation omitted). Second, the basis of Plaintiffs' allegations that they were "prescribed, injected with, and purchased Makena" are due to AMAG's "misrepresentations and material omissions" and AMAG failing to disclose Makena's ineffectiveness. (SAC ¶ 181). Third, and finally, this argument is closely related to the learned intermediary doctrine defense, which the Court has determined is inapplicable here.[15] Accordingly, the Court concludes that Plaintiffs' allegations are not "far too generalized" and do "place the defendant on notice of the precise misconduct with which it is charged." *Vandergroef v. Atl. Aviation Corp.*, No. 22-5920, 2023 WL 3173678, at *3 (D.N.J. May 1, 2023) (citations and internal quotations and brackets omitted).

6. The Second Amended Complaint Pleads Plausible Claims

a) The New Jersey CFA Claim (Count One)

The CFA "targets unlawful sales and advertising practices designed to induce customers to purchase merchandise or real estate." *Sun Chem. Corp. v. Fike Corp.*, 981 F.3d 231, 236 (3d Cir. 2020) (citation and internal quotations omitted). To that end, the CFA prohibits:

> The act, use or employment by any person of any commercial practice that is unconscionable or . . . misrepresentation, or the knowing, concealment, . . . or omission of any material fact with intent that others rely upon . . . in connection with the sale or advertisement of any merchandise . . . whether or not any person has in fact been misled, deceived or damaged . . . .

[15] *See* Section IV. D., *infra*.

N.J.S.A. 56:8-2.

To state a claim, Plaintiffs must allege: "(1) unlawful conduct; (2) an ascertainable loss; and (3) a causal relationship between the unlawful conduct and the ascertainable loss." *Francis E. Parker Mem'l Home, Inc. v. Georgia-Pacific LLC*, 945 F. Supp. 2d 543, 558 (D.N.J. 2013) (citation omitted). Unlawful conduct means "affirmative acts and knowing omissions," as well as "violations of regulations promulgated under" the CFA. *Id.* at 558 (citations omitted). "An omission occurs where the defendant (1) knowingly concealed (2) a material fact, (3) with the intention that the consumer rely upon the concealment." *Id.* at 559 (citations omitted).

Here, Plaintiffs allege that AMAG "misrepresented Makena's effectiveness at preventing preterm births[,]" constituting in part "unconscionable commercial conduct, deception, fraud, . . . misrepresentation, . . . or omission of a material fact with intent or reliance in connection with consumer sales of Makena . . . ." (SAC ¶¶ 190-91). Based on these allegations, Plaintiffs have sufficiently alleged unlawful conduct.

Next, Plaintiffs allege that they "suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff[s] . . . paid a premium price for Makena . . . ." (*Id.* ¶ 194). Also, that Maher "received approximately twenty weekly injections" of Makena, for which she "paid out of pocket[,]" from April 2019 to July 2019. (*Id.* ¶¶ 3-4). The out-of-pocket costs were allegedly $690 per shot or $10,917 for the duration of Maher's pregnancy. (*Id.* ¶¶ 73-74). These allegations are sufficient to allege ascertainable loss.

Finally, Plaintiffs allege that AMAG's actions or omissions caused Plaintiffs' ascertainable loss because they "were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections." (*Id.* ¶ 195). In assuming the truth of the allegations, Maher's ascertainable loss triggered by being "prescribed, injected with," and/or "purchas[ing]

Makena" (*Id.* ¶ 2), was caused by AMAG because it "misrepresented Makena's effectiveness at preventing preterm births." (*Id.* ¶ 190). Thus, contrary to AMAG's argument (AMAG's Br. at 76), these allegations are sufficient to allege a causal connection between AMAG's misrepresentations and Maher's ascertainable loss. Thus, Plaintiffs have sufficiently alleged the "causal relationship" element (third prong) with "particularity," "what misrepresentations [they] relied upon or when and how [they] w[ere] exposed to those misrepresentations." *Gray*, 2009 WL 1617930, at *3. Accordingly, the Court denies the motion as to Count One.

b) The UCL Claim (Count Two)

The State of California "provides an equitable means through which both public prosecutors and private individuals can bring suit to prevent unfair business practices and restore money or property to victims of these practices." *People v. Potter Handy, LLP*, 97 Cal.App.5th 938, 950 (Cal. App. First Dist., Div. 3 Dec. 8, 2023) (citation and internal quotations omitted). It does so by creating a cause of action for "unfair competition[.]" Cal. Bus. & Prof. § 17200. "Unfair competition" is defined as: (1) "any unlawful, unfair or fraudulent business act or practice[;]" (2) "unfair, deceptive, untrue or misleading advertising[;]" and (3) "any act prohibited by Chapter 1" of "Part 3 of Division 7 of the Business and Professional Code." (*Id.*).

To be "unlawful" under the UCL, the conduct "must violate another law." (AMAG's Br. at 78) (citation omitted). Plaintiffs allege that AMAG's conduct "violated the prohibition on making false or misleading statements in connection with the sale of prescription drugs found in 21 C.F.R. 202.1(e)(6-7) and 21 U.S.C. §§ 321(n), 352(a)." (Pls.' Br. at 52) (citing SAC ¶ 176). Also, that AMAG violated the CLRA (Count Three). (*Id.*). Thus, the unlawful prong is alleged.

Next, AMAG argues that Plaintiffs fail to allege facts sufficient to meet the "unfair . . . advertising" prong under the "tethering[,]" "balancing[,]" or "substantial" injury tests. (*See*

AMAG's Br. at 78-79). California courts are split between "which of three tests a court should apply to determine whether a business act that effects consumers (as opposed to competitors) is unfair within the meaning of the UCL." *Clark v. Prudential Ins. Co. of Am.,* 736 F. Supp. 2d 902, 930 (D.N.J. 2010) (applying California law) (internal quotations omitted).

The "tethering" test, which originally applied to unfairness to competitors rather than consumers, requires that "any finding of unfairness to competitors . . . be tethered to some legislatively declared policy or proof of actual or threatened impact on competition." *Clark*, 736 F. Supp. 2d at 930 (citation and internal quotations omitted).

The "balancing" test "defines an unfair business practice as one that violates established public policy or is immoral, unethical, oppressive or unscrupulous and causes injury to consumers which outweighs its benefits." (*Id.*) (citation and internal quotations and brackets omitted). When applying this test, courts "weigh the utility of the defendant's conduct against the gravity of the harm to the alleged victim." (*Id.*) (citation and internal quotations omitted).

The "substantial" injury test calls for application of a three-part test. (*Id.* at 930-31) (citation omitted). Specifically: "(1) the consumer injury must be substantial; (2) the injury must not be outweighed by any countervailing benefits to consumers or competition; and (3) it must be an injury that consumers themselves could not reasonably have avoided." (*Id.* at 930-31) (citation omitted).

In limiting their argument to the "balancing" test (Pls.' Br. at 52-53), Plaintiffs allege that AMAG's actions were "unfair" as they "caus[ed] Class members to make decisions based on false information . . . ." (SAC ¶ 202). Among their opposing arguments, AMAG contends that it "simply cannot be 'immoral' or 'unscrupulous' for AMAG to market Makena accurately and

consistent with its FDA-approved indication . . . ." (AMAG's Br. at 78-79). In applying the "balancing" test, the Court finds the "unfair" prong is met.

Plaintiffs argue that in "selling a drug at exorbitant prices to vulnerable pregnant women when one knows the drug is completely ineffective for its intended use, is immoral, unethical, or unscrupulous . . . ." (Pls.' Br. at 53) (internal quotations omitted). In viewing the allegations in the light most favorable to Plaintiffs, AMAG's actions may be "unfair in causing" Gomez and Torres "to make decisions based on false information[,]" which may be "fraudulent" because "AMAG knew or should have known its marketing statements were not true." (SAC ¶ 202). Further, Plaintiffs were injured by "undergo[ing] and purchas[ing] weekly injections of a drug that did not work . . . ." (*Id.* ¶ 204). Such allegations are sufficient to allege that AMAG's actions were "immoral, unethical, oppressive or unscrupulous" and, if proven, the "gravity of the harm to" Plaintiffs is significant. *See Backhaut*, 74 F. Supp. 3d at 1050 ("In determining whether a business practice is unfair under" the "balancing" test, California courts "balance the impact on its alleged victim against the reasons, justifications, and motives of the alleged wrongdoer.") (citation and internal quotations omitted); *see also Nolte v. Cedars-Sinai Med.* Center, 236 Cal.App.4th 1401, 1408 (2015). Accordingly, the Court denies the motion as to Count Two.

c) The CLRA Claim (Count Three)

AMAG argues that Count Three should be dismissed because the CLRA requires "written notice of the particular alleged violations . . . thirty days or more prior to the commencement of this action . . . ." (AMAG's Br. at 77) (citing Cal Civ. Code § 1782) (emphasis removed). Plaintiffs contend that adequate notice was provided and that because Plaintiffs amended their initial complaint "several times[,]" notice does not bar the claim. (Pls.' Br. at 51-52). Plaintiffs misinterpret § 1782(d).

To state a claim, a plaintiff must within "[t]hirty days or more prior to the commencement of an action for damages . . . [n]otify the person alleged to have employed or committed methods, acts, or practices declared unlawful by Section 1770[,] . . . [and] [d]emand that the person . . . rectify the goods or services alleged to be in violation of Section 1770." § 1782(a)(1)-(2). The notice must "be in writing . . . ." § 1782. If an action is commenced for injunctive relief, however, the action may be brought without written notice. § 1782(d) ("Not less than 30 days after the commencement of an action for injunctive relief, and after compliance with" the notice requirement, "the consumer may amend his or her complaint without leave of court to include a request for damages.").

Pertinent here, while § 1782(d) waives the notice requirement, it does so only where the initial claim was for injunctive relief and the amended complaint seeks only to add a claim for damages. Also, once the claim for injunctive relief is filed, the plaintiff must provide notice and only then, is free to amend the complaint to add the damages claim. *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 949 (S.D. Cal. 2007).

Here, Plaintiffs failed on both fronts. *See id.* at 949 ("[C]ompliance with" the notice "requirement is necessary to state a claim.") (citations omitted). Specifically, Plaintiffs sought damages in addition to injunctive relief in both the Amended Complaint and the Second Amended Complaint. (*See* ECF No. 15 ¶ 110; SAC ¶ 217, citing § 1780). Therefore, the Court does not find that an amendment to the claim is available. § 1782(d). Accordingly, to the extent the claim seeks relief beyond injunctive relief, including actual damages and punitive damages, the damages and punitive damages claims are dismissed with prejudice. *Laster v. T-Mobile USA, Inc.*, 407 F. Supp. 2d 1181, 1196 (S.D. Cal. 2005). However, the claim, is not dismissed to the extent it seeks injunctive relief only. The Court proceeds to whether Plaintiffs plead a plausible CLRA claim.

The CLRA "prohibits certain unfair acts and practices in a transaction intended to result or that results in the sale or lease of goods or services to any consumer." *Uyanik v. Wawanesa Gen. Insur. Comp.*, No. 22-16685, 2023 WL 8271964, at *2 (9th Cir. Nov. 30, 2023) (quoting Cal. Civ. Code § 1770(a)) (internal quotations and ellipses omitted). While the statute provides an exhaustive list of unlawful acts (*see* § 1770(a)(1)-(22)), Plaintiffs fail to identify which, if any, are triggered by the claim. *See Rubenstein v. Neiman Marcus Grp. LLC*, 687 F.App'x 564, 567 (9th Cir. 2017) (noting plaintiff stated a "plausible CLRA claim" in part under § 1770(a)(13)); *see also Boris v. Wal-Mart Stores, Inc.*, 649 F.App'x 424, 425 n.4 (9th Cir. 2016) (identifying § 1770(a)(4) as the basis for plaintiff's claim). And in reviewing the relevant allegations (*see* SAC ¶¶ 209-18), the Court is unable to determine whether Plaintiffs' allegations satisfy Federal Rule of Civil Procedure 8, a lesser standard than Rule 9(b).

Additionally, as to those Plaintiffs identified in support of the CLRA claim, Plaintiffs have not sufficiently pled reliance (SAC ¶ 209). *Park-Kim v. Daikin Applied Americas, Inc.*, 747 F.App'x 639, 640 (9th Cir. 2019). Though the Second Amended Complaint alleges Plaintiffs "would not have purchased and been injected with Makena" [b]ut for" AMAG's statements and/or omissions (SAC ¶ 177), this allegation does not excuse Plaintiffs' charge to allege a claim with specificity. Thus, as to the injunctive relief claim only, the Court dismisses it without prejudice.

d) The Missouri Act Claim (Count Five)

To state a claim under the Missouri Act, "a plaintiff must allege that she (1) purchased merchandise from the defendant; (2) for personal, family, or household purposes; and (3) suffered an ascertainable loss of money or property; (4) as a result of defendant's use of one of the methods, acts or practices declared unlawful by the Act." *Kelly v. Cape Cod Potato Chip Co.*, 81 F. Supp. 3d 754, 757 (W.D. Mo. 2015) (citing Mo. Rev. Stat. § 407.025.1). "[U]nlawful methods, acts or

practices include any deception, fraud, . . . misrepresentation, unfair practice . . . or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." *Id.* (quoting Mo. Rev. Stat. § 407.020.1) (internal quotations omitted). Here, AMAG contends that Plaintiffs failed to state a claim because they did not allege unlawful acts that caused them injury. (AMAG's Br. at 83-83). The Court disagrees.

Plaintiffs allege that AMAG "misrepresented Makena's effectiveness at preventing preterm births" which may qualify as a "misrepresentation" or an "omission of any material fact" under the Missouri Act. (SAC ¶¶ 229-30). Plaintiffs identify the alleged "false and deceptive" statements that may also be found to be an unlawful act under the Missouri Act. (*Id.* ¶ 231). Next, Plaintiffs contend that they "suffered an ascertainable loss caused by AMAG's misrepresentations" because they "paid a premium price for Makena . . . ." (*Id.* ¶ 233). Plaintiffs further allege that Barnes and Bonds "received marketing materials" and "pamphlets" about Makena, were "prescribed, injected with, and purchased Makena[,]" and "paid out of pocket for Makena." (*Id.* ¶¶ 221-28). Thus, the Second Amended Complaint pleads a plausible claim as to Bonds, as well as Barnes to the extent it relies on pre-March 8, 2019 allegations. Accordingly, the Court denies the motion as to Count Five.

e) The New York Business Law Claim (Count Six)

The State of New York outlaws "[d]eceptive acts or practices in the conduct of any business . . . ." NY Gen. Bus. § 349(a). To state a claim, a plaintiff "must allege: (1) the act or practice was consumer-oriented; (2) the act or practice was misleading in a material respect; and (3) the plaintiff was injured as a result." *Spagnola v. Chubb Corp.*, 574 F.3d 64, 74 (2d Cir. 2009) (citation omitted). "Deceptive practices are acts which are dishonest or misleading in a material respect." *Id.* at 74 (citation and internal quotations omitted).

In support of the first prong, the Second Amended Complaint alleges that in misrepresenting "Makena's effectiveness at preventing preterm births[,]" AMAG's "acts and practices were consumer-oriented" and "had the potential to effect even more consumers." (SAC ¶¶ 238-39). AMAG's statements, which Plaintiffs allege were "false and deceptive" (*Id.* ¶ 241), may be found to be deceptive practices or acts because they may mislead a reasonable consumer. This is enough.

While AMAG argues that statements in the Second Amended Complaint are not actionable, without explaining how each alleged statement is insufficient (*see id.* ¶ 241(a)-(f)), it contends that consumers could not "interpret them as a universal guarantee of Makena's complete effectiveness." (AMAG's Br. at 68). More specifically, that the statements are not actionable because Makena's website states that consumers' "experience with Makena may vary." (*Id.*) (citation and internal quotations omitted). This argument is unpersuasive as it assumes that the basis of the claim is that Plaintiffs took Makena under the impression that it was completely effective, and not that AMAG's statements are actionable under the New York Business Law.

In respect to the second prong, AMAG's alleged "deceptive, untrue or misleading advertising" and misrepresentations may be found to have mislead Plaintiffs in a material way because "[b]ut for" the same, Plaintiffs allege they would not have "purchased and been injected with Makena." (*Id.* ¶¶ 177, 240, 243). Such allegations are sufficient.

Finally, as to the third prong, Plaintiffs allege that they were injured by AMAG's deceptive acts or practices because they had to pay "a premium price" in purchasing Makena, "lost time associated with" being injected with Makena, and "were repeatedly and painfully injected with" Makena. (*Id.* 243-45). AMAG argues that this element is not sufficiently alleged because

Plaintiffs had to have "seen the misleading statements" before purchasing Makena. (AMAG's Br. at 70) (citation and internal quotations omitted). Even if true, the prong is satisfied.

Plaintiffs allege that Vargas "received Makena marketing materials/pamphlets in each shipment of Makena that was mailed to her home" and that she "had several telephone conversations" with "Makena Care Connection during" her treatment. (SAC ¶¶ 33-34). Because AMAG concedes that a claim under the New York Business Law does not need to satisfy Rule 9(b)'s heightened pleading requirements (AMAG's Br. at 67), such allegations are sufficient to meet the prong. Whether Vargas' purchase and injection of Makena were caused by her viewing the marketing materials and pamphlets and/or the telephone conversations, is for another day.

Accordingly, the Court finds a plausible claim as to Vargas. The same is not true of Faughnan and Odommorris, for whom Plaintiffs failed to provide similar allegations. Thus, the claim is dismissed without prejudice as to Faughnan and Odommorris. The claim is also dismissed without prejudice as to Maltese to the extent it relies on pre-March 8, 2019 allegations.

7. Plaintiffs Fail to Allege Standing to Plead a RICO Claim

"To have standing under RICO, a plaintiff must show (1) that his business or property was injured (2) by reason of a violation of the racketeering statute." *DiGilio v. U.S. Xpress, Inc.*, 293 F. Supp. 3d 522, 525 (E.D. Pa. 2018) (citation omitted). A plaintiff "must additionally state" that "a RICO predicate offense not only was a but for cause of injury, but was the proximate cause as well." *St. Luke's Health Network, Inc. v. Lancaster Gen. Hosp.*, 967 F.3d 295, 300 (3d Cir. 2020) (citations and internal quotations omitted). AMAG raises an additional step in the analysis.

According to AMAG, Plaintiffs do not have standing under the "indirect purchaser rule" that "bars a downstream (or indirect) purchaser from bringing claims against upstream manufacturers[,]" which the Third Circuit applied in *McCarthy v. Recordex Serv., Inc.*, 80 F.3d

842 (3d Cir. 1996). (AMAG's Br. at 86) (internal quotations omitted). In *McCarthy*, the Third Circuit found "antitrust standing principles apply equally to allegations of RICO violations[,]" which "deny[] RICO standing to indirect victims." 80 F.3d at 855 (citations omitted). AMAG argues that under the "indirect purchaser rule[,]" Plaintiffs do not have standing because they cannot allege that they "purchased Makena directly from AMAG." (AMAG's Br. at 86).

Though Plaintiffs assert "no other Third Circuit decision has followed the *McCarthy* holding" (Pls.' Br. at 64), New Jersey District courts have. *See Rickman v. BMW of N. AM.*, No. 18-4363, 2020 WL 3468250, at *9-10 (D.N.J. June 25, 2020 (dismissing RICO claim under indirect purchaser theory). In *Rickman*, the court considered the Third Circuit's holding in *In re Avandia Marketing Sales Practices & Prods. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015), which Plaintiffs correctly note is missing from AMAG's brief. (Pls.' Br. at 65). *Avandia*, however, did not consider *McCarthy*, provides no analysis of standing for "indirect purchaser[s][,]" and "speaks [only] to reliance and causation . . . ." *Rickman*, 2020 WL 3468250, at *10.

Moreover, while *Avandia* concerns similar factual allegations, it does not undermine application of *McCarthy* here. *See Humana, Inc. v. Indivior Inc.*, No. 20-4602, 2021 WL 3101593, at *11 (E.D. Pa. July 22, 2021), *aff'd,* No. 21-2573, 2022 WL 17718342 (3d Cir. Dec. 15, 2022) (applying *McCarthy* and distinguishing *Avandia*). Indeed, courts in this District continue to rely on *McCarthy*. *See MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, 18-2211, 2019 WL 1418129, at *15 n.12 (D.N.J. Mar. 29, 2019) ("Relying on the binding precedent in *McCarthy*, *Holmes*, and others, this Court" concludes "Plaintiffs have failed to demonstrate circumstances warranting a departure from the precedent set and affirmed by authorities binding this Court.").

Further, in reviewing the allegations of *Avandia*, that case is distinguishable because plaintiffs there alleged that "physicians relied on GSK's misrepresentations in deciding to

prescribe Avandia and *would have prescribed Avandia to fewer patients had GSK not concealed Avandia's risks . . . .*" 804 F.3d at 636 (emphasis added). No such allegations are raised here. Also, unlike *Avandia*, Plaintiffs do not allege that AMAG "selectively manipulated data and scientific literature, . . . and intimidated physicians to publish false and misleading articles-all in order to increase [Makena] sales." *Id.* at 636. Similarly missing are allegations that third-party payers and pharmacy benefit managers "included [Makena] in their formularies and covered [Makena] at favorable rates in reliance on these misrepresentations by [AMAG]." *Id.* at 636.

Here, Plaintiffs allege physicians prescribed Makena and that they would not have been injured but for AMAG's misrepresentations. (SAC ¶¶ 258, 262, 264, 267, 269, 271, 273-74). In viewing the facts in the light most favorable to Plaintiffs, the Court infers that this is because the only way Plaintiffs could obtain Makena was through physicians prescribing the medication, who, according to Plaintiffs, were allegedly misled by AMAG as to the effectiveness and safety of Makena. Under such a theory, Plaintiffs' injuries, if any, may not be "too far downstream from the conduct of [AMAG] for Plaintiffs to proceed with a RICO claim." *MSP Recovery Claims, Series LLC v. Abbott Labs.*, No. 19-21607, 2021 WL 2177548, at *8 (D.N.J. May 28, 2021) (citation omitted); *see also Roche Diagnostics Corp. v. Smith*, No. 19-8761, 2022 WL 4596720, at *9 (D.N.J. Sept. 30, 2022) ("[P]laintiffs pleaded direct injury sufficient to satisfy RICO's standing requirement because the alleged fraudulent scheme could have been successful only if plaintiffs paid for the drug at issue, and this is the very injury that plaintiffs seek recovery for.") (internal quotations, brackets, and parenthesis omitted). This, however, is not alleged in the Second Amended Complaint. Therefore, the claim is dismissed without prejudice.

V. CONCLUSION

For the reasons set forth above, and as memorialized in the accompanying Order, AMAG's motion to consolidate and to stay pre-trial deadlines (ECF No. 107) is **GRANTED**. AMAG's motion to dismiss (ECF No. 79) is **GRANTED in part** and **DENIED in part** as follows.

Counts One to Three and Counts Five and Six that arose after March 8, 2019, are preempted; and are **DISMISSED without prejudice** as to Plaintiffs Amaro, Uribe, Gill, Barnes, Vargas, Maltese, and Brady. Counts One to Three and Counts Five and Six that arose after March 8, 2019, remain only as to Plaintiffs Maher, Gomez, Torres, Bonds, Faughnan, and Odommorris.

Count One as to Maher and Count Two as to Gomez and Torres remain to the extent the claims arose after March 8, 2019. Count Three's damages claim is **DISMISSED with prejudice**; and Count Three's injunctive relief claim as to Gomez and Torres is **DISMISSED without prejudice**. Counts Four and Seven are **DISMISSED without prejudice**.

Count Six is **DISMISSED without prejudice** as to Faughnan and Odommorris; **DISMISSED without prejudice** as to Maltese to the extent the claim arose prior to March 8, 2019; and remains as to Vargas to the extent the claim arose prior to March 8, 2019.

Count Eight is **DISMISSED without prejudice**. Count Five remains as to Bonds in its entirety; and as to Barnes to the extent the claim arose prior to March 8, 2019.

The Court strikes Paragraphs 193, 201, 213, 232, and 242 in the Second Amended Complaint (ECF No. 66).

Plaintiffs have 30 days from the date hereof to file an amended complaint that is consistent with this Opinion.

DATED: March 28, 2024

s/ Julien Xavier Neals
JULIEN XAVIER NEALS
United States District Judge